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<u>REMARKS</u>

Claims 1-11 are pending in the application, claims 8, 10, and 11 having been withdrawn by Examiner (Applicant submits erroneously as will be explained hereinbelow), and remaining claims 1-7 and 9 being rejected over Chang U.S. Patent No. 5,491,766. For reasons which will be explained, it is respectfully submitted that the rejection is in error and should be withdrawn. Accordingly, reconsideration is respectfully solicited.

Restriction Requirement

Turning first to the withdrawal of claims 8, 10, and 11 by Examiner, Applicant notes that the Response to the Restriction Requirement filed herein elected species A (Figure 1) and not species B (Figure 2) as alluded to in the Official Action. Species B of Figure 2 is the subject of claims 12-14 which were retained in the parent case, and ultimately issued, but which were canceled in this case. Moreover, Applicant did not merely argue that claims 1-11 are readable on species A, but a review of the restriction requirement in the parent application will show that Examiner there held that claims 1-11 read on species A (Figure 1). See Notice of Allowability mailed December 26, 2001 at page 2 entitled "Detailed Action" which states

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Figure 1 (claims 1-11); and Species II: Figure 2 (claims 12-14).

In the present case, the Official Action mailed October 3, 2003 said essentially the same thing by classifying the two species as "(A) Figure 1; (B) Figure 2."

Examiner has now suddenly taken the position that claims 8, 10, and 11 are no longer related to Figure 1 (i.e., species A) but provides no logical basis to do so. Indeed, the

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subject matter of claims 8, 10, and 11 reads on both species (Figures 1 and 2) and so readily belongs active in the present set of claims.

In this regard, the difference between Figures 1 and 2 is the presence or absence of the catheter in the drawing. Claims 12-14 which were elected in the parent include the catheter, whereas claims 1-11 hereof do not recite the catheter and so are directed to the needle and its tip protector (whether it includes a catheter or not in view of the comprising language of the claims). There is no basis, however, to assume that the features of claims 8, 10, or 11 are limited to the Figure 2 embodiment. The tab, superstructure and clip of the claims are shown as the same structure in both Figures. In this regard, Figure 1, shows a tab 18, superstructure 85 and metal clip 75, and so does Figure 2 with the same reference numbering.

As explained above, the distinction between the two species focuses on the presence or absence of the catheter in the Figures and whether or not the catheter is a positive element of the claims; the distinctions do not necessarily focus on the details of the structure of the tip protector per se. Under the circumstances, it is respectfully submitted that claims 8, 10, and 11 should not have been withdrawn. Moreover, as will be shown below, claim 1 is submitted to be allowable over the cited Chang patent thus entitling Applicant to reinstate claims 8, 10, and 11 which depend therefrom, in any event.

The Prior Art Rejection

Claims 1-7 and 9 stand rejected as anticipated by the Chang patent. That rejection is respectfully traversed. In particular, Examiner will note that the present claims call for a "means coupled to the needle cannula shaft impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point". As

a matter of law, that language must be construed to cover the structure shown in the present application and equivalents thereof.¹ The particular structure shown in the present application is either a crimp or an enlarged portion (such as a bump or projections) or other irregularity of the needle shaft. It is respectfully submitted that no such structure or its equivalent is shown in the cited Chang patent. Rather, the structure which limits the distal extent of travel of the tip protector in charge is a mesh or other elongateable material which extends from the base of the needle to the tip protector so as to limit its axial travel towards the distal end of the needle. That is not the same or equivalent structure to that shown in the present application.

Examiner takes the position that there is "a crimp" shown in the Chang patent and makes reference to "Figures 2c, 6a-6c". However, those do not show a crimp nor has one been found in the reference. Perhaps Examiner is misinterpreting the gasket in that reference as if it were a crimp or other affect on the needle. That is not the case. As can be seen in Figure 2A, there is an oval-shaped item 17 shown in the opening near the base of the tip protector. That is a reference to the gasket through which the needle projects. That oval stays in that location irrespective of whether the needle is projecting well through the tip protector with the needle tip well away therefrom (as in Figure 1) or within the tip protector over the needle tip (as in Figure 2C). If Examiner continues to maintain that there is a crimp in the needle, Applicant respectfully

¹ Ex Parte Akamatso, 22 USPQ2d 1915, 1921 (BPAI 1992) (Solicitor's argument that means clause expressly covers any and all structure for performing the function is precluded in view of 35 U.S.C. § 112, para. 6 which requires means clause to be construed to cover corresponding structure shown in the specification and equivalents thereof). That case also makes clear that Section 112, para. 6 "can not be ignored when a claim is before the PTO any more than when it is before the courts in an issued patent." Id. Accord, In re Donaldson, 29 USPQ2d 1845 (Fed. Cir. 1994), (in banc) (broadest reasonable interpretation in prosecution is limited by 35 U.S.C. § 112, para. 6).

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requests Examiner to point out precisely where that crimp is shown or described in the Chang reference.

Under the circumstances, it is clear that the Change reference does not include the recited means of claim 1 (and its dependent claims) such that the anticipation rejection can not stand.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and/or are in error and the case is now in condition for allowance. Accordingly, a formal Notice of Allowance is solicited at the earliest possible time.

If, for any reason, the foregoing does not place this case in condition for allowance, or if any questions remain, Examiner is respectfully requested to telephone undersigned counsel to discuss same.

Respectfully submitted,

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